

## **Example 1: Bioscience & Healthcare**

### **1. Team**

The PI is a cosmetic, plastic, and reconstructive surgery specialist at Vanderbilt University Medical Center (VUMC) in Nashville, TN. He has over 20 years of experience in the medical field and graduated from the University of Mississippi School of Medicine in 2002. His VUMC office accepts new patients and telehealth appointments.

The PI has engaged a local medical device studio to support further device design and prototyping for evaluation. The studio advances early-stage device innovation toward clinical use and has extensive experience with design, prototypes, development, and business planning to prepare new device ideas for funding and manufacturing.

### **2. Technology/Innovation Description**

The device is an implant parachute that solves issues associated with insertion of implants into the human body. The most important of these issues is the elimination of contamination that can result in substantial complications. This device improves the placement of several types of implants into the human body, the most common of which are breast implants. Breast implants come in the form of saline- or silicone-filled implants, as well as temporary tissue expanders. Other implants relevant to this device as it pertains to its use in insertion into the human body include gluteal (buttock) implants, calf implants, facial implants, skull implants, body implants, and other hardware. A preliminary device design and prototype has been constructed already.

### **3. Predicted Outcomes**

Throughout the project, the studio will host bi-weekly meetings with the client. These meetings will serve as opportunities to comprehensively review the work objectives, monitor the project schedule, track expenses, and assess resource requirements. The PI will furnish proof-of-concept prototypes as part of their involvement in the project. The project budget covers the creation of a prototype and encompasses one iteration. Any additional iterations that may be required will be presented with cost quotes separate from this application.

For this Phase 1 of the project, the prototypes are primarily intended for learning purposes. They will be constructed using readily available materials whenever possible. It is important to note that iterative adjustments to the design, materials, or manufacturing methods will likely be necessary to achieve full functionality and meet all established requirements.

As Phase 1 concludes, the studio and PI will jointly review the project's status. Based on this review, the subsequent steps for a potential Phase 2 will be determined, followed by the studio providing an updated proposal for this next phase.

#### **4. Commercial Targets**

The three main commercial targets are Mentor (J&J subsidiary), Sientra, and Allergan.

Mentor is a subsidiary of Johnson & Johnson that supplies surgical aesthetics products to plastic surgeons. The company is based in Santa Barbara, California and produces one of two silicone gel breast implants, titled Memory Gel, which was approved by the U.S. Food and Drug Administration (FDA) on November 17, 2006.

Sientra is a medical aesthetics company that develops and sells medical aesthetics products, including silicone gel breast implants, breast tissue expanders, and scar management products.

Allergan is an American, Irish-domiciled pharmaceutical company that acquires, develops, manufactures, and markets brand name drugs and medical devices in the areas of medical aesthetics, eye care, central nervous system, and gastroenterology

The PI has existing relationships with these three companies. They make up the majority of the implant market and have each indicated that the problem this technology solves is indeed a concern for them, but they would like to see additional data and testing done with a prototype. The studio has ideas for testing the prototypes once they have been created, so prototypes need to be built so testing can begin.

#### **5. Scope of Work**

The aim of this proposal is to engage the studio in the process of proposing design and material alternatives and subsequently creating prototypes based on the PI's research. The project's initiation involves the studio offering a list of team members and hosting a kickoff meeting to set the project in motion.

Regarding the design features, the studio will collaborate on conceptualizing design attributes, material options, and assembly techniques. Additionally, they may furnish the PI with stock material samples for pre-prototyping assessment. The PI will be responsible for other aspects of the project, such as intellectual property, regulatory requirements, reimbursement strategies, and business models during the review of design options. Collaboratively, the PI and the studio will choose the preferred design, materials, and assembly methods.

In the first step of prototype development, the studio will acquire stock materials and commercial products for retrofitting purposes. Within this context, the studio will assemble two to five initial designs for learning. Subsequently, at least one prototype will be provided to the client for their review and feedback.

As part of the prototype iteration process, feedback received will guide the acquisition of necessary materials for producing a second iteration prototype. Like the prior step, the studio will assemble two to five prototype designs for learning purposes. Importantly, they will present at least three of these designs to the PI for assessment.

Following the creation of these prototype iterations, a technical review will be jointly conducted by the studio and the PI. During this review, the lessons learned, essential enhancements, and the subsequent steps will be deliberated upon and outlined collaboratively.

## **6. Deliverables**

The project entails the creation of prototype devices, aiming to produce a total of three to five refined prototypes. Additional prototypes will also be developed throughout the design phase to enhance the development process. The project will encompass generating comprehensive CAD models, drawings, and prototype specifications to guide the development. Furthermore, valuable manufacturing insights will be gathered to inform the refinement and optimization of the prototypes.

## **7. Schedule**

< 3 months

## **8. Budget**

The cost for this project will be billed on a time and materials basis. The hourly rates for personnel and approximate effort over three-month project period are listed below:

Time – \$7,500

Principal Engineer \$ 190.00 x 5 hrs

Sr. Engineer / Sr. Innovation Manager \$ 160.00 x 9 hrs

Engineer II / Innovation Manager \$ 130.00 x 13 hrs

Engineer I \$ 100.00 x 16 hrs

Associate/ Technician \$ 70.00 x 26 hrs

Material – \$2,000

Total – \$9,500

Note: in cases where unforeseen and direct cost expenditures arise, the PI will have the option to request such expenses. These unexpected costs, such as custom mold tooling or advanced testing, will be quoted separately to ensure transparency and accurate financial planning. These costs will be separated from the activities outlined in this proposal.